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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/816,002

03/31/2004

David K. Lang

DDI-5032

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27777

7590

10/02/2007

PHILIP S. JOHNSON

JOHNSON & JOHNSON

ONE JOHNSON & JOHNSON PLAZA

NEW BRUNSWICK, NJ 08933-7003

EXAMINER

JOHNSON, JERROLD D

ART UNIT

PAPER NUMBER

3728

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/816,002

Applicant(s)

LANG ET AL.

Examiner

Jerrold Johnson

Art Unit

3728

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 2-5, 9, 10, 12, 13, 15 and 26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 6-8, 11, 14 and 16-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

Claims 2-5,9,10,12,13,15 and 26 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 30 July 2007.

With respect to withdrawn claims 2-5, these claims are drawn to the package body depicted in Fig. 19, the Examiner is not able to find support in the specification of the use of the device package of the elected species shown in Figs. 14A-C with the package body of Fig. 19. Accordingly, as there is no known relationship between these two species, the claims drawn to the package body of Fig. 19 are withdrawn as not corresponding to the elected species of Figs. 14A-C. Additionally, it is noted that Eldridge, Jr. et al. US 4,395,807 shows in Figs. 15-18 how a medical device package is incorporated into a package body having a regular circular array. Eldridge, Jr. et al. US 4,395,807 is herein set forth as extrinsic evidence of the relationship between a medical device package and a package body.

With respect to withdrawn claims 12 and 26, these claims set forth a rigid projection, as is shown in the species of the present application shown in Fig. 10A, and which is not shown in the elected species. Accordingly, these claims are withdrawn.

This requirement is made final.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,6,7,8,11,14,16,20,21 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipton US 4,985,034.

Lipton discloses the medical device package having a proximal end, a proximal cap 44 that is inherently capable of being breached (i.e. broken), a distal end having an integrally formed end “cap” (the end wall), opposing deformable projections 16 that may deform to an angle in relation to the body of 20 degrees to 80 degrees, and a frangible projection 14. Lipton further discloses the method of use limitations of claims 20,21 and 25 that set forth the use of the above recited elements.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17-19 and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipton US 4,985,034 in view of Examiner's Official Notice.

With respect to claims 17-19, these materials are not set forth in Lipton. However, these are all well known materials in medical storage devices for their known benefits. The applicant has cited references to this effect. Accordingly, it would have been obvious to one of ordinary skill to use these materials in the package of Lipton.


With respect to claims 22-25, again the Examiner submits that the tape 44 as is shown in Fig. 6 of Lipton and described in col. 5, lines 3-8 is inherently capable of being breached (broken), but there is no recitation of it actually being breached as is called for in these method claims. Lipton does set forth the purpose of tape 44 as being used to indicate sterility or lack of tampering. The Examiner takes Official Notice that breakable (breachable) foils are an art recognized equivalent structure in accomplishing these two purposes in medical devices: Sacherer US 6,497,845 and Magney US 4,180,162 provide extrinsic evidence of this assertion. Magney shows element 18 set forth as a pressure sensitive foil. Accordingly, the claims drawn to the breaching of the cap member do not define over Lipton.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerrold Johnson whose telephone number is 571-272-7141. The examiner can normally be reached on 9:30 to 6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 571-272-4562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JDJ

  
Mickey Yu  
Supervisory Patent Examiner  
Group 3700